



Docket No. J&J2078 CON1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Miri Seiberg et al.

Serial No. : 10/629,023

Art Unit: 2643

Filed : July 28, 2003

Examiner:

For : SERINE PROTEASE AND TOPICAL RETINOID COMPOSITIONS
USEFUL FOR TREATMENT OF ACNE VULGARIS AND
PRODUCTION OF ANTI-AGING EFFECTS

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Andrea L. Colby

(Name of applicant, assignee, or Registered Representative)

Andrea L. Colby

(Signature)

March 1, 2004

(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e)
(attached); or
- ☐ Please charge Deposit Account No. 10-
0750/ / the fee of \$180.00 as set forth
in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

☒ The relevance of those listed references which are not in the English language is as follows:

DE 1792508 = English Abstract

DE 4305460 = English Translation Provided

EP 0749293 = US 5,830,449

SU 1690764 = English Abstract

WO 94/19005 = English Abstract

WO 97/25059 = English Abstract

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/J&J2078CON1/ALC. This form is submitted in triplicate.

Respectfully submitted,



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DATED: *March 2, 2004*

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 2	Application Number	10/629,023
	Filing Date	July 28, 2003
	First Named Inventor	Miri Seiberg
	Group Art Unit	2643
	Examiner Name	
	Attorney Docket Number	J&J2078 CON1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		5,215,740	A	Domke et al.	06-01-1993	
		5,665,366	A	Rawlings et al.	09-09-1997	
		5,830,449	A	Afriat et al	11-03-1998	= EP 0 759 293
		5,834,290	A	Egelrud et al.	11-10-1998	
		5,962,015	A	Delrieu et al.	10-05-1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	† ⁶
		Office ³	Number ⁴	KindCode ⁵				
		EP	0 759 293	B1	L'oreal	10-07-1998	= US 5,830,449	N
		DE	17 92 508	A	Spofa Vereinigte Pharmazeutische	04-20-1972	English Abstract	N
		DE	43 05 460	A1	Scheller	8-25-1994		Y
		SU	1 690 764	A1	Flora Domestic Chem Prodn Assoc	11-15-1991	English Abstract	N
		WO	84/02846	A1	Advanced Drug Technology Corp	08-02-1984		
		WO	94/19005	A1	Scheller	09-01-1994	English Abstract	N
		WO	95/07688	A1	Unilever	03-23-1995		
		WO	97/25059	A1	Beiersdorf AG	07-17-1997	English Abstract	N
		WO	97/47283	A1	Active Organics, Inc.	12-18-1997		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/629,023
Filing Date	July 28, 2003
First Named Inventor	Miri Seiberg
Group Art Unit	2643
Examiner Name	
Attorney Docket Number	J&J2078 CON1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		STN, File Supplier, Karlsruhe, DE, File XP002073067, Chemical Abstracts, Vol. 127, AN=243233 (see abstract)	
		DATABASE WPI, Week 9206, Derwent Publications Ltd., London, GB; AN 92-043740 XP002073069 & HU 57 608 A (PATONAY ET AL.) (see abstract)	
		STN, File Supplier, Karlsruhe, DE, File XP002073068, Chemical Abstracts, Vol. 118, AN=154179 (see abstract) & JP 04 364 119 A (TSUMURA AND CO.)	
		Life Science 1995, Vol. 57, No. 13, pp 1293-1297 (1995) "Topical Delivery of Growth Hormone Releasing Peptide Using Liposomal Systems: An in Vitro Study Using Hairless Mouse Skin", Fleischer et al.	
		Analytical Biochemistry 162, 156-159 (1987), "Single Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", Chomczynski et al.	
		Depts. Experimental Medicine and Cancer Research & Pathology, pp 493-501, "Identification of Programmed Cell Death in Situ via Specific Labeling of Nuclear DNA Fragmentation" Gavrielle, et al.	1
		Journal of Investigative Dermatology, 83:110-113 (1984) Vol. 83, No. 2, "Topical and System Effects of Retinoids on Horn-Filled Utricle Size in the Rhino Mouse. A Model to Quantify "Antikeratinizing" Effects of Retinoids", Mezick, et al.	1
		Cutis Medicine for the Practitioner, Vol. 57, No. 15, "A Clinical Profile of Azelaic Acid" (January 1996)	
		Skin Research & Technology (1995) 1:68-73, "Skin Biomechanical Properties; in Vivo Evaluation of Influence of Age and Body Site by a Non-invasive Method", Couturaud, et al.	
		Cell Growth & Differentiation, Vol. 6, 239-250, (March 1995) "Apoptosis in Pam212, an Epidermal Keratinocyte Cell Line: A Possible Role for bcl-2 in Epidermal Differentiation", Marthinuss, et al.	
		Cell Growth & Differentiation, Vol. 6, 807-816 (July 1995) "A Secreted Serine Protease Can Induce Apoptosis in Pam212 Keratinocytes", Marthinuss, et al.	
		Developmental Dynamics 208:553-564 (1997) "Trypsin-Induced Follicular Papilla Apoptosis Results in Delayed Hair Growth and Pigmentation", Seiberg, et al.	
		Arch Dermatol Res (1991) 283:100-107, "The Rhino Mouse Model: The Effects of Topically Applied all-trans Retinoic Acid and CD271 on the Fine Structure of the Epidermis and Utricle Wall of Pseudocomedones", Bernerd et al.	
		British Journal of Dermatology (1990) 122, 525-529, "In Vivo Tretinoin-Induced Changes in Skin Mechanical Properties", Berardesca, et al.	
		Skin Pharmacol (1991) 4:65-73, "Quantification of Epidermal Histological Changes Induced by Topical Retinoids and CD271 in the Rhino Mouse Model Using a Standardized Image Analysis Technique", Bouclier, et al.	
		Pharmaceutical Research, Vol. 12, No. 8 (1995) "Influence of Nonionic Liposomal Composition on Topical Delivery of Peptide Drugs into Pilosebaceous Units: An In Vivo Study Using the Hamster Ear Model", Niemiec, et al.	1
		Science, Vol. 262 695-700 (October 29, 1993) "Programmed Cell Death and the Control of Cell Survival: Lessons from the Nervous System", Raff et al.	
		The Journal of Dermatology, Vol. 15: 252-256 (1988) "Whole Mount Technique: An Improved Hamster Ear Model to Evaluate Pharmacologic Effects on Sebaceous Glands", Motoyoshi	
		Handbook of Mouse Mutations with Skin and Hair Abnormalities, The Jackson Laboratory, Bar Harbor, Maine 291-312 (1994) "Chapter 22, The Hairless (hr) and Phino (hrh) Mutations, Chromosome 14", Sundberg	
		The Journal of Investigative Dermatology, 62:268-287 (1974) "An Overview of Acne", Kligman	
		Seminars in Cancer Biology, Vol. 6, pp 3-16 (1995) "Cell Death in Health and Disease" the Biology and Regulation of Apoptosis", Bellamy, et al.	
		Proc. National Academy of Science, USA, Vol. 93, pp 2239-2244 (March 1996) Review "The Molecular Biology of Apoptosis", Vaux et al.	
		Journal of American Academy of Dermatology 32:S31-41 (1995) "The Treatment of Acne: The Role of Combination Therapies" Berson, et al.	
		The FASEB Journal, Reviews, Vol. 9, pp. 1277-1287 (October 1995) "The Biochemistry of Programmed Cell Death", Kroemer et al.	
		British Journal of Dermatology 122, 607-614 (1990) "Mechanical Properties of Human Forearm and Volvar Skin", Elsner et al.	
		Statistical Method in Biological Assay, Third Edition, Charles Griffin & Co. Ltd., London, pp 69-105 (1978) Finney	
		Handbook of Non-Invasive Methods and the Skin, CRC Press, (1995) Chapter 14.1 pp 319-328, "Twistometry Measurement of Skin Elasticity, Agache", Serup et al.	
		The American Journal of Dermatopathology, Vol. 3, No. 2, (Summer 1981) "Tips for and Mostly by Technicians", Nygard et al., pp 199-201 "Luna's Technique" Kligman.	

Examiner Signature	Date Considered
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